



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
--------------------	-------------	-----------------------	------------------

09/025.690 02/18/98 HAUL N 5/1213

EXAMINER

NM11/1027

ROBERT P. RAYMOND
BOEHRINGER INGELHEIM CORPORATION
900 RIDGEBURY ROAD,
P O BOX 368
RIDGEFIELD CT 06877

BERNHARDT, F

ART UNIT

PAPER NUMBER

1611

DATE MAILED: 10/27/98

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☐ Responsive to communication(s) filed on _____
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire one month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-17 is/are pending in the application.
- Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☐ Claim(s) _____ is/are rejected.
- ☒ Claim(s) _____ is/are objected to.
- ☒ Claim(s) 1-17 are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

F Bernhardt

EMILY BERNHARDT
PRIMARY EXAMINER
GROUP 1200 1600

SEE OFFICE ACTION ON THE FOLLOWING PAGES--

Art Unit: 1611

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-6,11-12, drawn to compounds,compositions where Het=benzothiazole and Ar=phenyl,naphthyl or thienyl, classified in class 548, subclasses such as 178,180;class 514 subclass 367,etc. .
 - II. Claims 1-12, drawn to compounds,compositions where Het=benzimidazolyl and ~~Het~~^{Ar} as defined in group I, classified in class 548, subclasses such as 309.7;class 546,subclass 273.4;class 514, subclasses 338,400,etc. .
 - III. Claims 1-6,11-12, drawn to compounds,compositions where Het=indolyl,Ar= as defined in group I, classified in class 548, subclasses such as 504;class 514, subclass 425,etc. .
 - IV. Claims 1-4,11-12, drawn to compounds,compositions not provided for by I-III above but generically embraced, eg. Het as quinoxalines, pyridoimidazoles, quinazolines,etc.with varying Ar groups and Hets of I-III with Ar as thiazolylene,pyridinylen,pyrimidinylene,etc. classified in classes various such as class 544,546, subclasses various.
 - V. Claim 15, drawn to a method of use employing compounds of I-IV and an additional thrombolytic agent, classified in class 514, subclasses various as determined by the exact nature of active ingredients employed.

If group IV is elected further restriction to a particular Het group is required as well as Ar group (i.e. Ar as phenyl,naphthyl,thienyl or one of the remaining het rings defined).

Art Unit: 1611

If any of groups I-IV are elected further election of a single species is required to which claims may be limited should generic claims be found not allowable.

If group V is elected applicants must pick one of groups I-IV as the het/Ar ingredient and either rt-PA or streptokinase as the 2nd active ingredient and to elect ultimate species representative of the elected pair.

If one of groups I-IV are elected applicants may pick one of the following choices of use to be examined:

A. claims 13-14 drawn to thrombotic diseases.

B. claim 16 drawn to inhibition of tumors.

C. claim 17 drawn to inflammatory diseases.

The inventions are distinct, each from the other because of the following reasons:

Compounds of groups I-IV represent structurally diverse compounds which lack no substantial structural feature in common but rather vary at every possible location. They are separately classified as indicated above but are also additionally classified on the basis of the varying R groups permitted in each of these groups as well as the Ar groups. Art which may anticipate or render obvious one of these groups would not necessarily do the same for those remaining.

Compounds of I-IV are independent and distinct from group V since the compounds, compositions may be old or obvious while the complex combination may be patentable due to superior or new properties not found in the single active components of I-IV. Additionally, they are of different scope since E is narrower in claim 15. Thus different issues of

Art Unit: 1611

patentability may arise. Within group V there is more than one invention as the claim recites multiple combinations which require independent searches.

Inventions I-IV and A-C are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case more than one distinct use exists for the compounds being claimed as evident by the method claims. Additionally the method claims are of narrower scope than the compound claims. Art pertinent to compounds having CN as E would not be pertinent to method claims excluding such. Additionally, the methods of use urged would raise different issues of patentability- at the very least 112 issues regarding the sole reliance on in vitro inhibition of thrombin or related serine proteases as a reasonable predictor of in vivo treatment for uses as varied as stroke, tumors, inflammatory disorders.

A telephone call was made to Mr. Stempel on 9/17 after an initial, preliminary restriction was made on 8/5 to request an oral election, but did not result in an election being made. Mr. Stempel requested that it be set forth in writing.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Art Unit: 1611

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication should be directed to Emily Bernhardt at telephone number (703) 308-4714.

A facsimile center has been established for Group 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machine are (703) 308-4556 or (703) 305-3592.

E Bernhardt
EMILY BERNHARDT
PRIMARY EXAMINER
GROUP 1200-1600